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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,113	05/22/2007	Jon Lundberg	1506-1103	1236
466 7590 01/25/2011 YOUNG & THOMPSON 209 Madison Street Suite 500 Alexandria, VA 22314			EXAMINER LANDRY II, GERALD ERNEST	
			ART UNIT 3763	PAPER NUMBER
			NOTIFICATION DATE 01/25/2011	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

### Office Action Summary

**Application No.**

10/583,113

**Applicant(s)**

LUNDBERG ET AL.

**Examiner**

GERALD LANDRY II

**Art Unit**

3763

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 54-67, 95-97 and 101 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 54-67, 95-97 and 101 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 09/01/2010
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

#### Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 54-66, 95-97, and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,417,657 to Hauer in view of U.S. Patent No. 6,425,881 to Kaesemeyer.

Regarding claims 54-66, 95-97, and 101, Hauer teaches a device for insertion in a human or animal body or body cavity (**refer to figure 2**), the device having an inflatable and expandable means (**24**), wherein the device is a gastric tube, catheter, wound drain tube, or an intratracheal tube (**the device 10, satisfies these limitations and is capable of performing as a gastric tube, catheter, wound drain tube, or an intratracheal tube**), wherein the device is a vascular catheter port (**refer to entrance of lumen 16 as shown best in figure 9**), wherein the inflatable and expandable means comprise an inflatable cuff (**24**), a first end that connects to a fluid connection device (**lumen 16 connects into a drainage bag (not shown), refer to column 5 lines 23-25**). Hauer however, does not explicitly teach at least one low molecular antimicrobial compound (LMAC) having a molecular weight equal to or less than 250U, wherein the at least one component is inorganic nitrite and the second component is ascorbic acid or acetic acid; a liquid being selected from the group consisting of water, saline or any physiological buffer, and wherein the LMAC is selected from the group consisting nitric oxide (NO), NO<sub>2</sub>, N<sub>2</sub>O<sub>3</sub>, N<sub>2</sub>O<sub>4</sub>, HNO<sub>3</sub>, HNO<sub>2</sub>, NO<sup>+</sup>, NO<sup>-</sup>, O<sup>2</sup>, O<sub>3</sub>, singlet oxygen, H<sub>2</sub>O<sub>2</sub>, OONO<sup>-</sup>,

HOONO, NOCl, NOSCIN, NO thiocyanate, an OH radical and HOCl. Kaesemeyer however, teaches at least one low molecular antimicrobial compound (LMAC) having a molecular weight equal to or less than 250U, wherein the at least one component is inorganic nitrite (**figures 1A and 1B, column 8 lines 33-44**) and the second component is ascorbic acid or acetic acid; liquid being selected from the group consisting of water, saline or any physiological buffer, and wherein the LMAC is selected from the group consisting nitric oxide (NO), NO<sub>2</sub>, N<sub>2</sub>O<sub>3</sub>, N<sub>2</sub>O<sub>4</sub>, HNO<sub>3</sub>, HNO<sub>2</sub>, NO<sup>+</sup>, NO<sup>-</sup>, O<sub>2</sub><sup>2-</sup>, O<sub>3</sub>, singlet oxygen, H<sub>2</sub>O<sub>2</sub>, OONO-, HOONO, NOCl, NOSCIN, NO thiocyanate, an OH radical and HOCl (**column 17 lines 4-27**). It would be obvious to one of ordinary skill in the art at the time the invention was made to modify the solution of Hauer (**Hauer: Abstract: pharmaceutical agent**) with the solution of Kaesemeyer with the motivation of providing an alternate medicament to the patient as is well known in the art.

3. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,417,657 to Hauer in view of U.S. Patent No. 6,425,881 to Kaesemeyer, and in further view of U.S. Patent No. 5,049,140 to Brenner et al.

Regarding claim 67, Hauer in view of Kaesemeyer teach all of the limitations of claim 54 (**see above**), but does not explicitly teach a device having a concentration of one or more metal ions in the contents of the inflatable and expandable means or in the material or on the surface of the device, the concentration being sufficient to increase the antimicrobial effect. Brenner teaches a device having a concentration of one or more metal ions in the contents of the inflatable and expandable means or in the material or on the surface of the device, the concentration being sufficient to increase the antimicrobial effect (**Brenner: column 2 lines 35-48**). It would be obvious to one of ordinary skill in the art at the time the invention was made to

modify the device of Hauer with the concentration of metal ions as disclosed by Brenner with the motivation of providing an alternate antimicrobial surface/coating/solution as is well known in the art at the time of the invention.

### **Response to Arguments**

3. Applicant's arguments with respect to claims 54-67, 95-97, and 101 have been considered but are moot in view of the new ground(s) of rejection.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GERALD LANDRY II whose telephone number is (571)270-7409. The examiner can normally be reached on M-F, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/GEL/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763